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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,521

05/02/2005

Jurgen Dolderer

23136

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03/05/2008

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EXAMINER

SUTTON, DARRYL C

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,521	Applicant(s) DOLDERER, JURGEN	
	Examiner DARRYL C. SUTTON	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed 12/24/2007.

Claims 8-11 are cancelled. No new claims have been added.

Previous Rejections

Unless specifically repeated/maintained infra, all previous rejections are withdrawn.

Obviousness Rejection

Claims 12 and 13 were rejected under 35 USC 103(a) as being unpatentable over Hillman et al (USP 6,071,720) in view of Bianchi et al (Cancer. Res., 1998) and further in view of Wang et al (FEBS, 1997).

This rejection is maintained.

In response to applicant's argument that there is no suggestion to combine the references, in this case, one of ordinary skill in the art (Cancer research and treatment) would be one with advanced degrees. Both DRCPS and HERG of Hillman have similar functions, i.e. mediating rectifying delay-type potassium current, as disclosed by applicant (see page 6, Arguments). One of ordinary skill in the art would recognize the similar function of DRCPS and HERG despite the differences in structure and in level of activity (slow vs. fast activation and deactivation). Hillman et al. teaches that since DRPCS is expressed in both cardiac tissue and cancerous tissue it appears to play a

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role in cancer and antagonist of DRPCS may be administered to treat cancer. HERG is also expressed in both cardiac tissue and in a variety of cancer lines. One of ordinary skill in the art would also recognize the relationship between the function of delay-type rectifiers of potassium current and adenocarcinomas since an antagonist of DRPCS is used to treat adenocarcinomas in Hillman et al. It is known in the art that adenocarcinomas account for 90-95% of colorectal cancers. Bianchi teaches that HERG is highly conserved and plays a role in various tumor lines and tumor cells. Bianchi et al. teaches that adenocarcinomas possess a rectifier current that is both biophysically and pharmacologically similar to HERG current and that this current was blocked by E-4031. Wang et al. teaches that E-4031 acts as an antagonist of the HERG delay type potassium channel subunit. Therefore, one of ordinary skill in the art would reasonably establish a relationship between the rectifier current of adenocarcinomas and the HERG potassium channel subunit. Hillman et al. recognized that adenocarcinomas can be treated by antagonists of delay-type potassium channel subunits. Therefore, one of ordinary skill in the art would reasonably expect that an antagonist of the HERG delay type potassium channel subunit would also be able to treat adenocarcinomas.

Moreover, the examiner's position is consistent with recent developments in the case law which now permit an "obviousness to try" analysis under proper factual circumstances. Specifically, in [In] *KSR v. Teleflex*, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there are a finite number of identified,

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predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obvious to try" with a reasonable expectation of success, is permissible.

Here there are only two solutions – HERG delay type potassium channel subunit or DRCPS delay type potassium channel subunit. Therefore, it would have been obvious to try to treat cancer with a compound that inactivates HERG potassium channel subunits, knowing that inactivation of DRCPS can be used as a treatment for cancer. In addition, Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 84 USPQ2d 1285 (Fed. Cir. 2007) recognized that the similar function of compounds rendered them obvious over one another. Therefore, it would have been obvious to recognize a relationship between the two types of potassium channel subunits because of their similar function, i.e. mediating rectifying delay-type potassium current.

The examiner maintains the rejection of claim 13, obtaining biopsy of cancerous tissue, lymph nodes, or samples of bodily fluids such stool to perform assays to detect biomarkers of cancer is well known in the art. At the time of the invention, it would have been obvious to perform these steps for any biomarker of the cancer in a method of treatment. Since the HERG potassium channel subunit is highly conserved and plays a role in various tumor and cancer cell lines, it would have been obvious to perform the steps to detect the HERG subunits in a method to treat cancer.

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is

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(571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/D. C. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612